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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,010	10/05/2000	Eva A. Turley	910130.401C1	5697

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EXAMINER
LIU, SAMUEL W

ART UNIT	PAPER NUMBER
1653	18

DATE MAILED: 09/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/685,010	TURLEY ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 21-24, drawn to a method for treating a patient with a distinct type of inflammatory neurological disorder, where the disorder is (i) Parkinsons disease, (ii) Alzheimer disease, (iii) arthritis, (iv) multiple sclerosis, (v) inflammatory dermatosis, (vi) inflammatory bowel disease and (vii) inflammatory lung disease, are classified in class 514, subclass 2^+, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

II. Claims 11-18, drawn to a method for treating a patient with wounds, are classified in class 514, subclass 2^+, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

III. Claim 19, drawn to a method for treating cancer, are classified in class 514, subclass 2^+, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

IV. Claim 20, drawn to a method for treating kidney fibrosis, are classified in class 514, subclass 2^+, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

V. Claim 25, drawn to a method for treating obesity and obesity related disease, are classified in class 514, subclass 2^+, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

VI. Claim 26, drawn to a method for treating lupus disorder, are classified in class 514, subclass 2^+, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

VII. Claims 27-28, drawn to a method for treating cardiovascular disease, are classified in class 514, subclass 2^+, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

VIII. Claims 29-33, drawn to an antibody, are classified in class 530, subclass 387.1.

IX. Claims 34-36, drawn to a polypeptide comprising domains D1, D2, D3, D4, or D5 of receptor for hyaluronan-mediated motility (RHAMM), are classified in class 530, subclass, 300 and 514, subclass 2^+.

X. Claim 37, drawn to a method for treating or preventing diabetes mellitus, are classified in class 514, subclass 2^+, class 530, subclass 300 and 387.1, class 436, subclass 86, class 435, subclass 7.1, 320.1 and 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII and X are directed to different and/or distinct methods for treating disease states, a method of treating patient with a inflammatory neurological disorder, a method for treating a patient with arthritis, a method for treating a patient with inflammatory dermatosis, a method for treating a patient with wounds, a method for treating a patient with stenosis or restenosis, a method for treating cancer, a method for treating kidney fibrosis, a method for treating inflammatory lung disease, a method for treating obesity and obesity related disease, a method for treating lupus disorder, a method for treating cardiovascular disease. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Inventions I-XII, since they constitute patentably distinct inventions comprising methodologies (pathological states), starting material, objectives, clinical or

pharmacological considerations (e.g. dose, side-effect, toxicity etc.), ingredients, endpoint or/and treatment outcome. Therefore, each method is patentably distinct.

Invention VIII and IX are patentably distinct from one another because of the materially different structures of the compounds claimed. Invention IX (polypeptide) and Invention VIII (antibody) are distinct from each other because of the materially different structures of the compounds claimed. The Invention IX is drawn to polypeptide, while Invention VIII is drawn to immunoglobulin, a polypeptide. The biopolymers are patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use. Inventions IX (polypeptide) and Invention VIII (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Although antibody is belong to a types of polypeptide, antibody is glycosylated and its tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. Thus, the macromolecule of each invention would be expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use.

Invention VIII is related to each of inventions I –VII and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies can be used in surface plasma

resonance technique in which the antibodies are immobilized on the chip-gold surface for detecting real time protein-protein interaction, for example.

Invention IX is related to each of Inventions I –VII and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be used in proteinchip array to investigating a signal transduction pathway, for example.

Additional Election Under 35 USC 121

Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed peptide to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

(a) If any Group from Groups I – X are elected, applicant is required to elect one of domain D1, D2, D3, D4 or D5 of the receptor for hyaluronan-mediated motility (RHAMM) since each segment of the domain is structurally distinct/different from one another, e.g. D4 and 5 contain different sizes of basic motifs while the others do not (see Assmann, V. et al (1999) *J. Cell Sci.* 112, 3934); thus, the raised antibodies against one of each segment of the domain has a distinct pharmaceutical or therapeutic property and would result in different or distinct mode of therapy.

(b) If group I is elected, applicant is required under 35 USC 121 to elect one of (i) through (vii) as each disease is distinct and method of treatment would have, absent factual data to the contrary, different and distinct parameters to effect the treatment.

In each of (a) and (b) above, the response should also identify the claims readable thereon as directed to the elected invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Applicant is required that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the peptides are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL

SWL

August 20, 2002

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600